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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/042,930	10/18/2001	Markus Seyfried	9342-029-999	5320

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GENENCOR INTERNATIONAL, INC.
925 PAGE MILL ROAD
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EXAMINER

STEADMAN, DAVID J

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 12/13/2002

4

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/042,930	SEYFRIED ET AL.	
	Examiner	Art Unit	
	David J. Steadman	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4 and 46-59 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-4 and 46-59 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____. | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Application

Claims 1-4 and 46-59 are pending in the application.

Cancellation of claims 5-45 and addition of claims 46-59 in Paper No. 3, filed 10/18/01 is acknowledged.

Specification/Informalities

1. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. The following title is suggested: "Method of Fermenting Glycerol to 1,3-Propanediol Using a Thermophilic Organism". See MPEP § 606.01.
2. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 121 as follows: An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification (37 CFR 1.78). If applicant desires priority under 35 U.S.C. 121 based upon a previously filed co-pending application, specific reference to the earlier filed application must be made in the instant application. This should appear as the first sentence of the specification following the title, preferably as a separate paragraph. The status of nonprovisional parent application(s) (whether patented or abandoned) should also be included. If a parent application has become a patent, the expression "now Patent No. _____" should follow the filing date of the parent application. If a parent application has become abandoned, the expression "now abandoned" should follow the filing date of the parent application.

Claim Rejections - 35 USC § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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3. Claims 49, 60, and 61 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
4. Claim 49 is confusing in the recitation of "a mixture of nitrogen and carbon dioxide in a ratio of about 80 to about 20". In order to clarify the ratios of the individual gases, it is suggested that applicants replace the term "a mixture of nitrogen and carbon dioxide in a ratio of about 80 to about 20" with, for example, "a mixture of nitrogen to carbon dioxide in a ratio of about 80 to about 20".
5. Claims 60 and 61 are indefinite in the recitation of "wherein the genome of the thermophilic organism is at least 95 % identical to the genome of the organism deposited as ATCC designation PTA-584" or "wherein the genome of the thermophilic organism is at least 99 % identical to the genome of the organism deposited as ATCC designation PTA-584" as it is unclear how one compares the sequence identity of two genomes. Although it is possible to compare sequences of specific nucleic acids within the genome of an organism, the examiner can find no such sequence listing(s) in the specification, figures, or claims of the instant specification.

Claim Rejections - 35 USC § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1-4 and 46-59 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1, 2 (claim 53 dependent therefrom), 46-52, and 54-59 are directed to a method of converting glycerol to 1,3-propanediol using a genus of thermophilic organisms, thermophilic organisms

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having a genome at least 95 % or 99 % identical to the genome of PTA-584, or thermophilic organisms having a 16S rDNA sequence at least 95 % or 99 % identical to the genome of PTA-584. Claim 3 (claim 4 dependent therefrom) is drawn to the method of claim 2, further comprising a step of polymerizing the 1,3-propanediol into a genus of polymers. The specification teaches only 1 representative species of thermophilic organisms that convert glycerol to 1,3-propanediol, i.e., PTA-584 and only a single species of polymer produced from 1,3-propanediol, i.e., PPT. Moreover, the specification fails to describe any other representative thermophilic organisms with the ability to convert glycerol to 1,3-propanediol or polymers produced by 1,3-propanediol by any identifying characteristics or properties other than the functionality of being thermophilic organisms with the ability to convert glycerol to 1,3-propanediol or polymers produced by 1,3-propanediol. Given this lack of description of representative species encompassed by the genus of the claim, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that applicants were in possession of the claimed invention.

7. Claims 1-4 and 46-59 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of converting glycerol to 1,3-propanediol using PTA-584 and optionally converting the 1,3-propanediol to PPT, does not reasonably provide enablement for a method of converting glycerol to 1,3-propanediol using any thermophilic organism, any thermophilic organism having a genome at least 95 % or 99 % identical to the genome of PTA-584, or any thermophilic organism having a 16S rDNA sequence at least 95 % or 99 % identical to the genome of PTA-584, and optionally converting the 1,3-propanediol produced by a thermophilic organism into any polymer. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

Undue experimentation would be required for a skilled artisan to make the invention using the entire scope of recited thermophilic organisms and optionally using the produced 1,3-propanediol to make the entire scope of recited polymers. Factors to be considered in determining whether undue experimentation is required, are summarized in *In re Wands* (858 F.2d 731, 8 USPQ 2nd 1400 (Fed. Cir.

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1988)) as follows: (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claim(s).

Claims 1, 2 (claim 53 dependent therefrom), 3 (claim 4 dependent therefrom), 46-52, and 54-59 are so broad as to encompass a method of converting glycerol to 1,3-propanediol using *any* thermophilic organism, *any* thermophilic organism having a genome at least 95 % or 99 % identical to the genome of PTA-584, or *any* thermophilic organism having a 16S rDNA sequence at least 95 % or 99 % identical to the genome of PTA-584, and optionally converting the 1,3-propanediol produced by a thermophilic organism into *any* polymer. The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of thermophilic organisms and polymers broadly encompassed by the claims. In this case the disclosure is limited to a method of converting glycerol to 1,3-propanediol using PTA-584 and optionally converting the 1,3-propanediol to PPT.

The specification provides guidance and working examples for converting glycerol to 1,3-propanediol using only PTA-584 and optionally converting the 1,3-propanediol to only a single polymer, i.e., PPT. The specification does not provide guidance as to other polymers that can be produced from 1,3-propanediol and/or conditions for polymerization that would predictably yield other polymers. The specification does not provide guidance as to other thermophilic organisms that convert glycerol to 1,3-propanediol and, at the time of the invention, the state of the art would indicate that such thermophilic organisms were not commonly known to a skilled artisan. Regarding claims 54-57, while the specification provides primers for amplification of the 16S rDNA of PTA-584, the specification does *not* provide the sequences of the 16 rDNA or the entire genome of PTA-584. These sequences are necessary for isolation of other thermophilic organisms having the recited limitations as broadly encompassed by claims 54-57. While 16S rDNA sequences were known to be used for phylogenetic comparisons at the time of the invention, it was not common to compare an organism's entire genome, particularly an organism whose genome was yet to be disclosed or made publicly available, which would certainly require undue

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experimentation. Furthermore, Stackebrandt teaches (*Phylogeny Based on 16S rRNA/DNA*, Encyclopedia of Life Sciences, pages 1-7, Nature Publishing Group, New York, 2001) that only a minor change in the 16S rDNA sequence of a prokaryotic organism (1 % or approximately 15 nucleotides) may significantly alter the physiological and biochemical properties of the organism (page 7). Based on the absence of thermophilic organisms reported to have the ability to convert glycerol to 1,3-propanediol and the teachings of Stackebrandt, one of skill in the art would recognize the high degree of unpredictability that any thermophilic organism, any thermophilic organism having a genome at least 95 % or 99 % identical to the genome of PTA-584, or any thermophilic organism having a 16S rDNA sequence at least 95 % or 99 % identical to the genome of PTA-584 would have the ability to convert glycerol to 1,3-propanediol and the undue experimentation that would be required to make the entire scope of recited thermophilic organisms.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make the claimed invention in a manner reasonably correlated with the scope of the claims broadly including a method of converting glycerol to 1,3-propanediol using *any* thermophilic organism, *any* thermophilic organism having a genome at least 95 % or 99 % identical to the genome of PTA-584, or *any* thermophilic organism having a 16S rDNA sequence at least 95 % or 99 % identical to the genome of PTA-584, and optionally converting the 1,3-propanediol produced by a thermophilic organism into *any* polymer. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

8. It is noted that the instant invention employs a novel microorganism described in the specification as ATCC Deposit Number PTA-548. Applicants state the deposit has been made in accordance with the Budapest Treaty (see page 37 of the instant specification). Applicants have previously provided a statement of public availability of ATCC Deposit Number PTA-584 as Paper No. 18

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in parent application 09/405,692. Therefore, the requirements for biological deposit of ATCC Deposit Number PTA-584 have been fulfilled.

Double Patenting

9. Claims 1, 2, and 46-59 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 6 and 71-79 of co-pending Application No. 09/405,692. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1, 46-52, and 54-59 of the instant application are generic to all that is recited in claims 6 and 71-79 of 09/405,692. In other words, Claims 1, 46-52, and 54-59 of the instant application are anticipated by claims 6 and 71-79 of 09/405,692. While the limitations of claims 2 and 53 of the instant application are not anticipated by claims 6 and 71-79 of 09/405,692, it would have been obvious to one of ordinary skill in the art to collect the produced the 1,3-propanediol (claim 2) or further purify the produced 1,3-propanediol (claim 53).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

10. Claims 3 and 4 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 6 of co-pending Application No. 09/405,692 in view of Doerr et al. (US Patent 5,340,909). Doerr et al. teach a method for polymerizing 1,3-propanediol to PPT (columns 7-9, Examples 1-3). Doerr et al. also describe the commercial usefulness of PPT in the production of racquet strings, composite matrices, carpets, films, etc. (columns 2 and 3). Based on the teachings of Doerr et al., it would have been obvious to one of ordinary skill in the art to convert glycerol to 1,3-propanediol using PTA-584 and polymerize the produced 1,3-propanediol to form PPT. One of ordinary skill in the art would have been motivated to polymerize the produced 1,3-propanediol into PPT for commercial use as described above. One would have a reasonable expectation of success for converting glycerol to 1,3-propanediol using PTA-584 and polymerizing the produced 1,3-propanediol to form PPT because of the teachings of Doerr et al.

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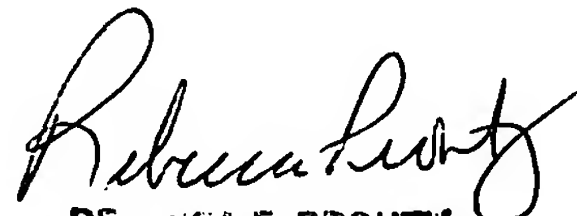
This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

11. All claims are rejected. No claim is in condition for allowance.
12. The examiner requests that applicants provide a copy of all pending claims in the response to this Office action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Steadman, whose telephone number is (703) 308-3934. The Examiner can normally be reached Monday-Thursday from 6:30 am to 5:00 pm. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (703) 308-3804. The FAX number for this Group is (703) 308-4242. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Art Unit receptionist whose telephone number is (703) 308-0196.

David J. Steadman, Ph.D.
Patent Examiner
Art Unit 1652


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